WORK ASSIGNMENT 0-02

Title: Technical Support for New and Existing Chemicals Fate and Exposure Assessments

Contractor: SRC, Inc. **Contract No.:** EP-W-12-003

Estimated Period of Performance: Date of issuance through December 31, 2012
Estimated Level of Effort: 400 hours

Key EPA Personnel:

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PURPOSE:
The purpose of this work assignment is to provide technical support in four areas of effort: (1) Provide fate support for the preparation of the Initial Review Exposure Reports (IRER) for new chemicals; (2) Provide technical support for the development, review, analysis, and presentation of environmental fate and transport and exposure assessments for existing chemicals under TSCA and other Agency initiatives; (3) Provide technical support for the update of standard operating procedures for conducting the fate and exposure assessment of Nanomaterials; and (4) Provide technical support for the development, review, analysis, and presentation of environmental fate and transport and exposure assessments for Nanomaterials under TSCA and other Agency initiatives. This work assignment does not duplicate any work previously performed for similar efforts.

BACKGROUND:

The Exposure Assessment Branch (EAB) of the Economics, Exposure and Technology Division develops the guidance for and/or produces screening-level and/or detailed chemical fate and exposure profiles and information summaries for both new and existing chemical projects within the Office of Pollution Prevention and Toxics (OPPT). OPPT's new chemical projects reside in the New Chemicals Program under section 5 of the Toxic Substances Control Act (TSCA). OPPT's existing chemical projects may originate in various programs, including but not limited to those associated with SIDS (Screening Information Data Set), the Existing Chemicals Action Plans, TSCA Section 21 petitions, and OPPT test rules. This work may include environmental fate assessments for Nanomaterials.

The Scope of Work for Specific Tasks under this Work Assignment:

Task 1: Submit Work plan and Budget; manage Work Assignment and Administrative Tasks

This task will involve the submission of a work plan and budget, and the management of the work assignment. As specified in the contract, the contractor shall prepare a work plan within 15 calendar days of receipt of this assignment. The work plan shall describe the work to be performed, the technical approaches used for the various tasks, projected schedules, cost information, a staffing plan, and an outline of key deliverables on a task-by-task basis with expected due dates.

The contractor shall notify the EPA WAM within 30 days of the work assignment's hours and approved budget being 75% and 90% exhausted.

The contractor shall immediately inform the EPA WAM of any problem that may impede performance during the period of this task.

Task 2: Prepare a Quality Assurance Project Plan (QAPP)

The contractor shall produce a QAPP as part of its work plan for this work assignment.

Task 3: Preparation of Meeting Attendance and Reports

If requested in the written technical directions from the EPA WAM, the contractor shall attend meeting and teleconferences with the EPA WAM at EPA offices and other locations as part of this work assignment. The scheduling of these meetings will be designated by the EPA WAM. The contractor shall prepare summary notes describing each meeting's topics, action items, and decisions; the contractor shall provide the summary to the WAM within one business day of the meeting.

The contractor shall maintain copies of all work documentation including: templates, assumptions, raw data, calculations, and information used or produced during the course of any task in this work assignment. Communication via e-mail is preferred with the e-mails being maintained as a written record.

Task 4: Preparation of Fate portion of Initial Review Exposure Reports (IRER) for New Chemicals

EAB is responsible for preparing IRER as the first step in EAB's review of new chemicals, including nanotechnology submissions. For a standard new chemical submission that is a discrete organic substance, preparing the fate assessment portion of the IRER involves estimating and recording relevant physical/chemical properties prior to the Chemical Review and Search Strategy (CRSS) meeting and then preparing the complete report prior to the Structure Activity Team (SAT) meeting. The properties are used in assessing the environmental fate and the potential exposure and hazard associated with the PMN substance. It is essential that these estimates are prepared prior to presentation of the PMN substance at the CRSS meeting. The full fate assessment report must be prepared prior to the SAT meeting which occurs the day following CRSS.

The contractor shall prepare the fate assessment portion of the IRER reports for the upcoming biweekly CRSS and SAT meetings, or as requested for other chemicals in written technical direction from the WAM, including nanotechnology products. Otherwise, preparing each report involves two steps:

First, the contractor shall estimate the physical/chemical properties using EPI (Estimation Programs Interface). This is done for all chemicals that have a suitable structure given in the PMN. Also, the contractor shall use any environmental fate data or p-chem properties given in the PMN that are noted and used, where appropriate, in making the estimations. The contractor shall enter this data into a DATA database.

Second, after the CRSS meeting, the contractor shall combine the CRSS and DATA databases using the ISIS program. The resulting FATE database contains the structure, measured and estimated p-chem property data, and other EPI estimates of the environmental fate of the substance. The FATE database provides the basis for the IRER report which the contractor shall print on the appropriate three-page form provided by the EPA WAM.

In the case of nanotechnology products, the contractor shall employ alternate tools and methods as specified under the written technical guidance of the Work Assignment Manager (WAM). The contractor will review the literature, identify and implement alternate methods for conducting fate and exposure assessments for nanotechnology products using specific written instructions from the WAM in a technical direction document.

The contractor shall also include in each report a summary of fate data extracted from the PMN submission. The contractor shall extract data for the following tests: biodegradation, hydrolysis, soil/sediment sorption, photolysis and possibly other tests specified by the work assignment manager in written technical direction. The contractor shall enter this data into an ISIS database which will later be added to the FATE database.

The contractor shall enter the appropriate p-chem and environmental fate information developed for each IRER into the PMN Notes tracking system for each submission.

Task 5: Technical Support for Development of Environmental Fate, Transport and Exposure Assessments for Existing Chemicals

The contractor shall provide technical support for the development of environmental fate, transport and exposure assessments for existing chemicals as required to conduct screening level or detailed assessments as described in the bullets below:

The subject areas to be addressed under this subtask include

- environmental fate and transport
- exposure assessment
- environmental monitoring
- environmental fate testing
- analytical chemistry
- experimental design and statistics

The activities the contractor shall conduct under this subtask include

- development of preliminary fate and/or exposure assessments
- literature searches
- review and summary of existing literature
- statistical and/or technical evaluation of scientific reports
- summary of data and preparation of presentation materials
- development of data repositories

To initiate work under this subtask, the WAM will contact the contractor by telephone to provide specific information on the support requirements and a more specific schedule for delivery. These instructions will also be provided to the contractor in writing by the WAM within three (3) business days of approval of the work assignment.

Task 6: Technical Support for the Revision and Update of Environmental Fate and

Exposure Assessments Methods for Nanomaterials

1) The contractor shall search the Office of Research and Development (ORD) Nanotechnology database, the open literature, and any other sources specified by the WAM in written technical direction and identify any relevant non-occupational exposure and fate studies that may be used to update assessment methods.

2) The contractor shall identify and review existing environmental fate and p-chem (physical-chemical) property test methods, and environmental fate and exposure assessment methods used or proposed by regulatory authorities, scientific or environmental organizations.

3) The contractor shall summarize relevant methods and make recommendations for their modification, if necessary, and incorporation into revisions of the Exposure Assessment Branch's Interim Technical Guidance (ITG) for nonmaterial's assessments.

4) The contractor shall make recommendations for how to update the SOP as new information on the fate of nanomaterials is developed.

5) After discussion with the WAM, and as specified in written technical direction, the contractor shall revise the existing ITG document and template/format for nanomaterials fate and exposure assessments. The contractor shall redraft a revised ITG to include the method, rationale, and references for EAB's approach to the following:

    a. Transport and transformation of nanomaterials in the atmosphere
    b. Transport and transformation of nanomaterials in surface water and groundwater
    c. Transport and transformation of nanomaterials in soil
    d. Behavior/removal of nanomaterials in wastewater treatment plants
    e. Behavior/removal of nanomaterials in drinking water treatment plants
    f. Bioaccumulation potential of nanomaterials
    g. Potential for nanomaterials to transform to more toxic products
    h. Interaction of nanomaterials with environmental contaminants and potential for the nanomaterial-contaminant combination to affect bioaccumulation of the contaminant and/or nanomaterial
    i. Exposure to nanomaterials

The contractor shall note in the ITG where insufficient information exists to conduct specific parts of the fate and exposure assessment and suggest approaches to addressing any data gaps.

Task 7: Technical Support for Conducting Fate and Exposure Assessments for Nanomaterials

The contractor, following written instructions from the WAM, shall provide technical support to the WAM for nanomaterials fate and exposure assessment work under programs including TSCA Section 5 (PMN).

The technical support may include the following and the contractor shall conduct the following as specified in written instructions from the WAM:

1) The use of previously identified methods to conduct preliminary fate and exposure assessments for nanomaterials.

2) The review and summarization of new information submitted to EPA in support of TSCA Section 5 (PMN) assessments.

3) Collection and analysis of other relevant information identified by the WAM in written technical direction in support of the assessments.

Task	Deliverable	Schedule
Task 1: Submit Work plan and Budget; manage Work Assignment and Administrative Tasks	- Work plan	15 calendar days after receipt of work assignment
Task 2: Develop and Implement a Quality Assurance Plan for the Period of Performance	- Quality Assurance Project Plan required for data evaluation and model development and updates.	- 30 calendar days after assignment by WAM through written technical direction
Task 3: Meeting Attendance and Reporting Requirements	- meeting participation, reports, presentations, etc.	- Described in Technical Directions
Task 4: Prepare P Chem and Fate portions of Initial Review Exposure Reports	P-Chem and fate pages of Initial Review Fate Reports	- Described in Work Assignment
Task 5: Provide Technical Support for Development of Environmental Fate, Transport and Exposure Assessments for Existing Chemicals	Supporting reports, information, etc. as required by technical directions	- Described in Technical Directions
Task 6: Provide Technical Support for the Revision and Update of	Supporting reports, information, etc. as required	- Described in Technical Directions

Environmental Fate and Exposure Assessments Methods for Nanomaterials	by technical directions	
Task 7: Provide Technical Support for Conducting Fate and Exposure Assessments for Nanomaterials	Supporting reports, information, etc. as required by technical directions	- Described in Technical Directions

OTHER INFORMATION:

Contractor personnel shall at all times identify themselves as contractor employees, and shall not present themselves as EPA employees. Furthermore, they shall not represent the views of the US Government, the EPA, or its employees. In addition, the contractor and its employees shall not engage in inherently Governmental activities, including, but not limited to, actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondence.